

ORIGINAL ARTICLE

Is a speculum examination sufficient for excluding the diagnosis of ruptured fetal membranes?

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Objective. To determine the false negative rate of a sterile speculum examination for the diagnosis of rupture of the membranes in women not in labor and without visible amniotic fluid at speculum examination. Furthermore, possible risks to the mother and the baby after suspected rupture of the membranes were analyzed.

Study design. In women not in labor with suspected rupture of the membranes between gestational weeks 34 and 42, a sterile speculum examination was performed. If no amniotic fluid was visible, a test for Diamine oxidase was carried out. The results of tests were not known to the obstetricians or the women. The women were allowed to return home with no further controls if no amniotic fluid was visible at the speculum examination. Neonatal and obstetric outcome was recorded prospectively.

Results. Of 27,502 deliveries, 2,099 women not in labor attended the delivery ward for suspected rupture of the membranes after week 34. Amniotic fluid was visualized in 1,580 women. In 519 women in whom no amniotic fluid was seen at the speculum examination, the Diamine oxidase test was negative in 456 and positive in 63. Antibiotics were given to eleven children (2.4 %) in the group with a negative Diamine oxidase and to one infant (1.6 %) in the positive Diamine oxidase group ($p > 0.05$). No differences in obstetric outcome were recorded.

Conclusions. The false negative rate of a speculum examination for the diagnosis of rupture of the membranes in women without amniotic fluid visible at a speculum examination was 12 % when Diamine oxidase was used as the standard for the diagnosis of rupture of the membranes. This study did not show any disadvantages for mothers and infants if the women were sent home after a false negative speculum examination. The value of biochemical methods in the management of women not in labor with rupture of the membranes after thirty-four weeks of gestation could be questioned.

Key words: amniotic fluid; diagnosis; fetal membranes; premature rupture; prospective study

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Prelabor rupture of the membranes (PROM) at term occurs in 5–10% of all pregnancies. One common problem is how to diagnose rupture of the membranes (ROM) because there is no generally

accepted method for diagnosing ROM. A number of methods such as the identification of lanugo, staining for lipids, identification of fetal cells, pH determination, analysis of DAO and arborization have been developed to detect amniotic fluid. The commonly used nitrazine paper had a false positive rate of 17.4% and a false negative rate of 9.7% and the Fern method had a false positive rate of 5.8 % and a false negative rate of 12.9% in a study

Abbreviations:

DAO: Diamine oxidase; ROM: rupture of the membranes, PROM: Prelabor rupture of the membranes; FN: fetal fibronectins.

by Friedmann (1). Studies have shown that the analysis of Diamine oxidase (DAO) had a false positive rate of 0–2% and a false negative rate of 0–1% (2, 3). However, the analysis of DAO has not been widely used, mainly because there has not been a rapid test available, and the method has been time-consuming. Diamine oxidase (DAO) is an enzyme which is absent from normal vaginal secretions and urine but so abundant in amniotic fluid that 10 µl absorbed on a paper strip is easily measurable (3). A sensitive test such as DAO can detect even small quantities of amniotic fluid, but it can be questioned whether a small membrane leak of amniotic fluid is of clinical significance (3).

The aim of the present trial was to study the false negative rate using a sterile speculum examination for the diagnosis of ROM. In addition, we wanted to evaluate possible risks to the mother and the baby if the women were allowed to return home without any further controls if no amniotic fluid was visible at the speculum examination.

Subjects and methods

Women not in labor admitted to the labor and delivery unit with self-reported suspicion of ROM between 34 and 42 weeks of gestation were regarded as eligible for the study provided the following inclusion criteria were fulfilled:

1. admitted to the delivery ward for suspected rupture of the membranes,
2. no amniotic fluid visible at the speculum examination,
3. estimated gestational age of 34 weeks or more (always based on an ultrasound examination before 20 weeks of gestation),
4. singleton with the fetus in cephalic presentation,
5. a normal fetal heart rate tracing,
6. normal pregnancy.

Women were excluded if the pregnancy was abnormal, for example: antibiotic therapy for Group B streptococcal colonization, suspicion of intra-uterine growth retardation (estimated fetal weight on ultrasound more than 25 % below the normal

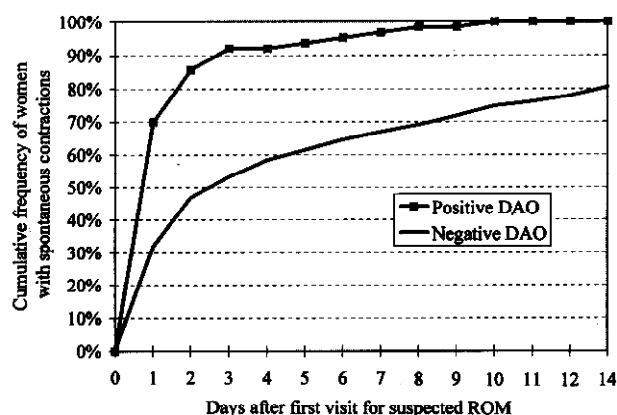


Fig 1. Women without visible amniotic fluid at the speculum examination in two different groups according to the result of the DAO test. The lines show the cumulative frequency (%) in which spontaneous contractions occurred after their first visit for suspected PROM. The duration is expressed as days.

weight), severe preeclampsia, bleeding, or chorioamnionitis.

At admission, a speculum examination was performed and, if no amniotic fluid was visible, a test for DAO was conducted. A strip of absorbent paper (10×65 mm) was introduced into the vagina, and was withdrawn when it was soaked wet and placed in a tube for later analysis. Digital examinations of the cervix were avoided until labor. The women were observed for two hours walking around with a sanitary towel. If there were no signs of amniotic fluid after this period of time, the women were sent home. If signs of amniotic fluid were suspected on the sanitary towel, another speculum examination was performed, but, if no amniotic fluid could be visualized, the patient returned home.

The DAO activity was determined with ¹⁴C-Putrescine as the substrate, as described by Elmfors and Tryding (2). The laboratory analyzed the tests continuously and the results of the DAO tests were not known to the obstetricians or to the women. The results of the DAO analysis were not available until the trial was finished. Clinical data regarding mothers and babies were collected prospectively.

The women were classified as having ROM if there was a positive test for Diamine oxidase activity.

The main parameter analyzed was the false negative rate of a speculum examination for diagnosing ROM when DAO was used as a standard. The study was approved by the Ethics Committee, Faculty of Medicine, University of Göteborg.

Wilcoxon's rank-sum test was used to compare differences between the groups. Proportions were compared using Fisher's exact test. A *p*-value of

Table 1. Characteristics of women included in the trial

	Amniotic fluid not visible, negative DAO <i>n</i> =456	Amniotic fluid not visible, positive DAO <i>n</i> =63
Age (years)	27.1 (4.7)	27.5 (5.2)
Gestational age (weeks)	39.7 (2.3)	39.6 (1.3)
Birth weight (g)	3,642 (499)	3,615 (483)
Nulliparous	228 (50%)	28 (44%)

Results are mean (s.d.) of *n* (%) as appropriate

<0.05 was considered statistically significant. SAS statistical software was used for analysis.

Results

Of the 27,502 deliveries from March 1989 until March 1993, a total of 2,099 women attended the delivery ward for suspected ROM without contractions after 34 weeks of gestation. Amniotic fluid was visualized in 1,580 women and, in 43 of them, there were signs of intact membranes at delivery. The outcome for these women has previously been reported (4). In 519 women, no amniotic fluid was visible at the speculum examination and a test for DAO was conducted. Two different groups were compared:

1. negative DAO (0–0.15 pkat/l),
2. positive DAO (>0.15 pkat/l).

The baseline characteristics of the women in the groups are summarized in Table I. No significant differences could be detected between the groups in terms of age, gestational age, birth weight and parity.

In 456 women DAO was negative and in 63 a positive DAO was found. A speculum examination had a false negative rate of 12% when DAO was used as a standard for diagnosing ROM.

The mean time interval from the first visit for suspected ROM until contractions started was 179 (range 1–1104) hours for the group with negative DAO and 63 (range 1–240) hours for the positive DAO group ($p < 0.0001$). Most women with a positive DAO returned to the delivery ward a short time later with contractions. Ninety-two percent had contractions within 72 hours (Fig. 1). No differences in obstetric outcome between women with a positive or a negative DAO were detected (Table II).

One woman had signs of chorioamnionitis during labor and she had a negative DAO taken 19 days before the delivery. No other maternal infections of significance were detected. No differences in neonatal outcome between the two groups were found (Table III).

Table II. Obstetric outcome

	Negative DAO <i>n</i> =456	Positive DAO <i>n</i> =63	Odds Ratio (95% CI)
Oxytocin use	165 (36%)	23 (36%)	0.99 (0.70–1.41)
Spontaneous delivery	414 (91%)	55 (87%)	1.04 (0.94–1.15)
Ventouse extraction	6 (10%)	2 (10%)	1.09 (0.24–4.97)
Cesarean section	11 (2.4%)	3 (4.8%)	0.05 (0.15–1.77)

Results are *n* (%)

Table III. Neonatal outcome

	Negative DAO <i>n</i> =456	Positive DAO <i>n</i> =63	<i>p</i> -value
Apgar score at 5 min. <7	5 (1.1%)	0	1.00
SCBU ¹ -admission	40 (8.9%)	5 (8.1%)	1.00
Days at SCBU ¹	5.5 (6.5)	1.8 (1.3)	0.11
Antibiotics	11 (2.4%)	1 (1.6%)	1.00
Perinatal mortality	0	0	

Results are mean (s.d.) or *n* (%) as appropriate.

¹ SCBU=Special Care Baby Unit.

Discussion

Women admitted for suspected ROM is a common problem in a delivery ward. In addition to ROM, the reasons for 'non-specific fluid' could be urine, semen or cervical mucus. A speculum examination as the only method for the diagnosis of ROM was used in this study, but it may produce some false negative results. To study the false negatives the analysis of DAO was used because of the high specificity and sensitivity of this test reported in previous trials (2, 3). No increase in maternal or fetal morbidity was detected in women sent home after a false negative speculum examination. Accordingly, it seems plausible that amniotic fluid leakage in these women was of minor or no clinical significance.

Studies during the period 1960–80 revealed an increased risk of maternal and perinatal mortality when the time interval from rupture of the membranes until delivery was prolonged (5, 6). Since the studies from that period reported a high fetal and maternal morbidity, the problem of false positive results from the different tests of ROM may have been of minor importance.

Recent studies in which patients have been managed without an initial digital examination indicated a low risk of infectious morbidity after ROM, even with conservative management (4, 7, 8). Accordingly, a test with a high percentage of false positives can subject the patient to iatrogenic risks such as unwarranted augmentation of labor and possible failed induction.

In this study, the use of a speculum examination for the diagnosis of ROM showed an acceptable frequency of false negatives when the analysis of DAO was used as a standard for the diagnosis of ROM. The morbidity in the false negative group was not raised. Most previous studies have only included patients in whom the diagnosis of ROM has been absolutely certain. However, women who are not in labor and present with non-specific vaginal fluid loss is the specific group of interest

when the accuracy of a method for the diagnosis of ROM should be evaluated.

The commonly used amniotic fluid crystallization test (fern test) was reported to have a false positive rate of 11.8 % and a false negative rate of 2.0 % when the study was conducted in women in labor with rupture of the membranes (9). In the same study, 120 women presented with non-specific vaginal fluid loss and in this group the false positive rate of 21 % and a false negative rate of 41 % was reported for the Fern test.

The measurement of fetal fibronectins (fFN) has been shown to be a method for detecting ROM. An immunoassay which determined fFN in vaginal secretions using monoclonal antibodies was used by Salfelder and coworkers (10). Thirty-four of 35 patients with clearly visible amniotic fluid in the vagina had a positive test result (97.1%), whereas the majority of the control group without any signs of ruptured membranes had negative test results (96.5%). Thirty-nine of 41 women with a positive test delivered within 48 hours. The limitation of Salfelder's study was that it was not based on women with suspected ROM. Beckmann et al. (11) used the visualization of indigo carmine at speculum examination after an intraamniotic injection of indigo carmine as the standard for the diagnosis of ROM. They studied 65 patients, but 12 patients had to be excluded from the study for various reasons. Indigo carmine and fFN showed identical results in 50 patients, while fFN was positive in three cases with a simultaneous negative result from the intraamniotic dye injection. Recently Nisell et al. (12) concluded that the determination of fetal fibronectin is of no benefit in the management of women with equivocal ROM.

A study which would elucidate whether there are any benefits in using a test for ROM should be prospectively designed and include women without evident ROM at the speculum examination. The results of the test should not be known to the obstetrician before delivery and outcome measures should be recorded. If patients with a positive test show a worse outcome compared with those with a negative test, the test may be of value in clinical practice.

This study showed that a speculum examination for diagnosing ROM had an acceptable frequency of false negatives. The risk of infectious morbidity was not increased if the women were sent home after a speculum examination when no amniotic fluid was detected. Although the sample size was small, the findings in this trial may indicate that the value of biochemical methods for the diagnosis of ROM has been overestimated. Before new and costly methods for diagnosing ROM are introduced, studies involving a sufficient number of

women are needed to show the possible benefits are warranted. Until now, no such studies have been published.

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